

The Food and Drug Administration (FDA) is responsible for the licensure of new vaccines, ensuring that the new vaccines meet requirements for safety, purity, potency, and efficacy. The licensing process encompasses the FDA's evaluation (Investigational New Drug Application), monitoring and evaluating the vaccine during the different stages of clinical trial, and granting a license if appropriate. Additionally, during the licensing process, the FDA establishes standards and criteria for the release of each vaccine lot. The FDA is responsible for the lot release of each vaccine and uses its laboratories to conduct lot release tests, such as the neurovirulence test for polio and the potency test for pertussis. The FDA is responsible for the periodic inspection of vaccine manufacturing facilities and the monitoring and evaluating of vaccine adverse effects; it also is responsible for overseeing compliance with its regulations. To help carry out its mission, the FDA maintains an active research program in vaccine-related topics, and convenes workshops and symposia related to vaccine functioning and testing.

The Health Resources and Services Administration (HRSA) supports the provision of immunizations through HRSA-funded primary care programs and through the Maternal and Child Health Block Grant program. It also supports immunizations through the Healthy Start initiative.

HRSA'S Bureau of Primary Health Care (BPHC) funds immunizations as a component of comprehensive primary care services offered through funded Community and Migrant Health Centers (C/MHCs). The BPHC is collaborating with the CDC'S National Immunization Program to ensure adequate vaccine supplies for C/MHCs and to undertake several evaluation and demonstration projects. The bureau also is working with the Corporation for National Black Churches and the Department of Agriculture's Cooperative Extension Service to train and utilize volunteers to assist local health and social service programs in reaching medically underserved people with services, including immunizations.

The Bureau of Maternal and Child Health (MCH) administers the Maternal and Child Health Block Grant programs which supports 59 States and jurisdictions in the provision of health care services to targeted populations on a three-for-four match. For FY 1994, \$574.5 million has been appropriated for State grants as part of the MCH Block Grant program. The bureau also administers Special Projects of Regional and National Significance (SPRANS) and Community Integrated Service System (CISS) projects, which add an additional \$112.5 million for a total of \$687 million in the MCH Block Grant. A substantial portion of MCH Block Grant funds are used by States to enhance the delivery of immunizations as a part of comprehensive child health services provided at local health departments.

The Healthy Start initiative is a demonstration program that provides resources and technical assistance for 15 urban and rural communities with infant mortality rates of between 1.5 and 2.5 times the national average. Its goal is to reduce infant mortality by 50 percent in these selected high-risk areas by October 1996. For FY 1994, \$97.4 million has been appropriated for comprehensive child health services, including immunizations.

Included within HRSA'S Bureau of Health Professions is the Division of Vaccine Injury Compensation, which is responsible for the HHS medical reviews and payment of claims filed under the National Vaccine Injury Compensation Program. The Secretary of Health and Human Services is represented by Department of Justice attorneys in proceedings before the U.S. Court of Federal Claims.

The Indian Health Service (IHS) carries out its responsibilities to provide immunization services for the Native American population through development and operation of a health care services delivery system that integrates preventive health into an overall system of health care. Preventive health services are delivered by IHS tribally managed or urban Indian health care facilities. For the most part, the States provide vaccines for IHS clients.

The National Institutes of Health (NIH) supports investigation on all classes of infectious diseases. NIH is made up of 14 Institutes, 11 of which support vaccine research for both infectious diseases and noninfectious diseases, including autoimmune disease and cancers. Intramural laboratories focus on vaccine research. Clinical evaluation of candidate vaccines is complemented by extensive collaboration with industry. Centers support the investigation of key areas of vaccinology. Together with a program of basic research on the human immune system, these centers nurture a comprehensive and collaborative vaccine effort among extramural scientists in government, industry, and academic institutions.